510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name: X-spine Systems, Inc.
452 Alexandersville Rd.
Miamisburg, OH 45342

Telephone (937) 847-8400
FAX (937) 847-8410

Official Contact: David Kirschman, M.D.
Chief Medical Officer

DEC 11 2013

Date Prepared: December 5, 2013

DEVICE NAME

Trade/Proprietary Name: Certex™ OCT Spinal Implant System
Common Name: Spinal Implants
Classification Name: KWP 888.3050 – Appliance, Fixation, Spinal Interlaminal

ESTABLISHMENT REGISTRATION NUMBER

X-spine Systems, Inc. has submitted an Establishment Registration to FDA. The Establishment Registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INTENDED USE

The intended use of the Certex OCT Spinal Implant System is to promote fusion of the occipito-cervico-thoracic regions of the spine (Occiput – T3 inclusive). The indications for use are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e., fracture or dislocation),
- Spinal Stenosis,
- Atlanto-axial fracture with instability,
- Failed previous fusion,
- Occipito-cervical dislocation,
- Revision of previous cervical spine surgery,
- Spinal tumors.

The occipital bone screws are limited to occipital fixation only.

The hooks and rods are intended to provide stabilization and promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic spine (C1-T3).

The use of the polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) for purposes of anchoring an OCT construct, and are not intended for treatment of thoracic conditions. Screws are not intended to be placed in the cervical spine.

DEVICE DESCRIPTION

The Certex OCT Spinal Implant System consists of screws, hooks, rods, plates and connectors. Various sizes of these implants are available so that adaptations can be made to take into account pathology and individual patient anatomy. The Certex OCT Spinal Implant System components are manufactured from Titanium alloy in accordance with ASTM F136 and will be provided clean but non-sterile.

PREDICATE DEVICES

- X-spine Systems, Inc. – Certex Spinal Implant System (K122163)
- Aesculap, LLC – S4 Cervical Occipital Plate Spinal System (K062012)

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Certex OCT Spinal Implant System is substantially equivalent to predicate devices based on a comparison including the following characteristics:

- FDA Product Code
- Intended Uses
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

PERFORMANCE DATA

The implant components were tested using the following testing standards per FDA Guidance and recommendations:

- ASTM F2706 – *Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model*
  - Static and dynamic compression
  - Static and dynamic torsion
- ASTM F1798 – *Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*
  - Axial Slip
  - Torsional Slip

In summary, results from the biomechanical testing indicate that the Certex OCT Spinal Implant System is substantially equivalent to predicate device performance and is capable of performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2013

X-spine Systems, Incorporated
David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K133094
Trade/Device Name: Certex™ OCT Spinal Implant System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 6, 2013
Received: December 9, 2013

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133094

Device Name
Certex™ OCT Spinal Implant System

Indications for Use *(Describe)*
The intended use of the Certex OCT Spinal Implant System is to promote fusion of the occipito-cervico-thoracic regions of the spine (Occiput – T3 inclusive). The indications for use are as follows:

- Degenerative Disc Disease (as identified by neck or back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Zane W. Wyatt -S